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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,031	12/11/2003	Robert Zaczek	BMS-PH-7048-A(C)	8984

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PILLSBURY WINTHROP SHAW PITTMAN, LLP  
P.O. BOX 10500  
MCLEAN, VA 22102

EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/734,031	<b>Applicant(s)</b> ZACZEK ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10,13-18,20-22,36-49,54-65 and 70-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,13-18,20-22,37,38,40-49,54-65 and 70-77 is/are rejected.
- 7) ☒ Claim(s) 36 and 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/3/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 10/17/05 wherein claims 6, 14, 16, 17, 22, 37-42, 44-49, 55, 57, 58, 63-65, 75, and 76 are amended and claims 11, 12, 19, 23-35, 50-53, and 66-69 are canceled.

**Note:** Claims 1-10, 13-18, 20-22, 36-49, 54-65, and 70-77 are pending.

## **RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT**

2. The Applicant's arguments filed 10/17/05 to the rejection of claims 1-10, 13-18, 20-22, 36-49, 54-65, and 70-77 made by the Examiner under 35 USC 103, 112, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **Double Patenting Rejections**

I. The rejection of claims 1, 6, 17, 18, 20, 22, 54, and 55 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 6,878,363 is MAINTAINED for reason of record in the office action mailed 7/13/05.

II. The rejection of claims 1-6, 9, 10, 13-18, 20, and 21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of US Patent No. 6,331,408 is MAINTAINED for reason of record in the office action mailed 7/13/05.

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III. The provisional rejection of claims 1-6 and 59-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-7, 29, 34-42, 46-50, and 52 of application number 11/018,331 is MAINTAINED for reason of record in the office action mailed 7/13/05.

**Note:** It is duly noted that in Applicant's response filed 10/17/05, the double patenting rejections were not addressed.

**112 Rejections (New Matter)**

The rejection of claims 6-10, 41-49, 54-65, and 70-77 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 7/13/05.

(1) Applicant asserts that some of their other applications initially contained the same definition for the instant aryl groups since there are no C7, C8, or C9 aryls it was indicated that the use of C6-C10 aryl was improper. (2) In addition, Applicant asserts that the seeming limitation on aryl is actually an inadvertent error.

In response to assertion (1) above, the term 'C6-C10 aryl' is not improper because one may have substituted aryl groups. (2) Since C6-C10 aryls are possible based on the fact that you may have a substituted aryl group that results in the presence of 6-10 carbon atoms, the limitation on aryl as being a C6-C10 aryl from the Examiner's perspective and the disclosure of the specification is not viewed as an error.

**112 Rejections (Enablement)**

The 112 rejection (enablement) is WITHDRAWN.

**112 Rejections (Second Paragraph)**

I. The 112 rejection (second paragraph) over claim 6 is WITHDRAWN.

II. The rejection of claim 14 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 7/13/05 and those below.

Applicant asserts that the fragment of the amyloid peptide producing enzymes have been specifically identified as inhibitor binding.

Applicant's argument is not persuasive because the issue is not whether the peptide has a binding site but what the actual peptide is. In other words, what fragment/derivative is Applicant referring to? The rejection may be overcome by deleting 'or any fragment or derivative thereof'.

III. The rejection of claims 37, 38, 55, 57, and 58 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 7/13/05 and those below.

Applicant asserts that the fragment of the amyloid peptide producing enzymes have been specifically identified as inhibitor binding.

Applicant's argument is not persuasive because the issue is not whether the peptide has a binding site but what the actual peptide is. In other words, what fragment is Applicant referring to? This rejection may be overcome by deleting 'or any fragment thereof'.

IV. The 112 rejections (second paragraph) over claims 64 and 76 are  
WITHDRAWN.

## **NEW GROUNDS OF REJECTIONS**

### **112 Rejections**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17, 64, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17: The claim as written is confusing because of the phrase 'disorders involving similar to Alzheimer's Disease, accumulative'. In particular, it is unclear if the condition of interest is Alzheimer's Disease or some similar disease. The rejection may be overcome by replacing 'degenerative neurological disorders involving similar to Alzheimer's Disease, accumulative beta-amyloid production' with 'Alzheimer's Disease'.

Claims 64 and 76: The claims as written contain improper Markush terminology. Applicant is respectfully requested to review MPEP 803.02. The claims are also ambiguous because they read on any compound since the phrase 'found capable of binding...compounds' is not a positive recitation. Thus, the phrase is not given patentable weight for a product claim.

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**Note:** The recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such limitation does not constitute a limitation in any patentable sense (*In re Hutchison*, 69 *USPQ* 138).

### **CLAIM OBJECTIONS**

5. Claims 36 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **COMMENTS/NOTES**

6. The claims are free of the art of record for reasons of record in the office action mailed 7/13/05. However, Applicant **MUST** address and overcome the double patenting and 112 rejections above.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

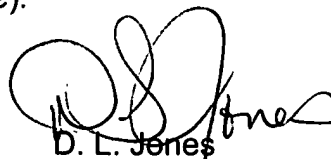
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1618

January 6, 2006